REMARKS

Claims 1-16, 21-23, 28-49 and 67-85 are pending in this application. Claims 22, 23, 28-49 and 67-84 were previously withdrawn. Claim 12 has been cancelled and amendments to Claims 1 and 13 and New Claim 86 are proposed Support for these amendments is found in the specification as filed. These amendments introduce no new matter. By the amendments, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

In addition, Applicants have submitted herewith an Information Disclosure Statement. Applicants submit the IDS in response to Examiner's statement that the Zhou et al., reference was not considered because it was not of record. Office Action at 7. In addition, to respond to Examiner's rejections, Applicants have cited one U.S. Patent and t two on-line dictionary definitions and those references are also submitted in the IDS.

I. CLAIM REJECTIONS ON THE GROUND OF NONSTATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING

The Examiner has provisionally rejected Claims 1-16, 21 and 85 as not patentably distinct from Claims 1, 10, and 34-53 of U.S. Patent Application Serial No. 11/003,006 in view of Campbell [Cloning & Stem Cells, 3(4): 201-208)]. Office Action at 3. Applicants respectfully traverse.

Applicants maintain their position that Examiner's rejection is improper for the reasons stated in their response to the Office Action dated August 15, 2006. Applicants also assert that the rejection should be held in abeyance pending the allowance of claims in both pending applications. The Examiner has instructed that a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting ground. Without acquiescing to the propriety of the Examiner's rejection, and specifically the Examiner's interpretation of what the cited references teach or claim, Applicants respectfully and properly defer addressing the present rejection until there is allowable subject matter in the present application. At that time, a terminal

disclaimer will be filed if warranted by the Examiner's rejection in view of the allowed claims. However, to expedite prosecution Applicants agree to file a terminal disclaimer over pending Claims 1, 10, and 34-53 of co-pending Application Serial No. 11/003,006, should such become necessary and appropriate.

II. CLAIM REJECTIONS UNDER 35 U.S.C. § 112, ¶1.

The Examiner rejected Claims 1-16, 21 and 85 under 35 U.S.C. § 112, ¶1, for failing to comply with the enablement requirement. Office Action at 5-13. Specifically, the Examiner stated:

> In view of the state of the art of [nuclear transfer ("NT")], particularly with regard to the unpredictability of donor cells and recipient cells to be used, where the state of the art only supports specific cell types with regard to successful NT, the state of the art of primate NT, wherein art at the time of filing shows that improper spindle formation is perhaps not the only cause for developmental arrest of primate NT embryos, the post-filing art that shows that primate NT remains unpredictable, the lack of teachings or guidance provided by the specification, with regard to the one or more molecular components that would be added to the nuclei to produce a viable embryo, it would have required undue experimentation, for one of skill in the art, to determine the parameters, cell types, molecular components necessary to achieve [somatic cell nuclear transfer "SCNT"], as broadly claimed.

Office Action at 12-13. Applicants respectfully traverse.

A. The Examiner Errs by Improperly Requiring that the Claimed Methods Produce a Cloned Animal.

As a starting point, the Examiner's rejection and attendant analysis was based upon a faulty premise; namely, that the claims require production of a cloned animal. In this regard, the Examiner has continued to mischaracterize the claimed invention. Although acknowledging that Applicants deleted the language "producing a cloned animal," the Examiner proceeded to interpret the term "viable primate embryo" to require production of a cloned animal. The Examiner's interpretation is demonstrably incorrect.

"Because a patent specification must enable the full scope of a claimed invention, an enablement inquiry typically begins with a construction of the claims." *Chiron v. Genentech*, 363 F.3d 1247, 1254 (Fed. Cir. 2004) (quotations and citations omitted). "[T]he words of a claim are generally given their ordinary and customary

meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc) (internal quotations and citations omitted). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* Moreover, during prosecution the Examiner is to give claims "their broadest reasonable interpretation consistent with the specification." Manual of Patent Examination Procedure § 2111. The Examiner failed to heed these instructions in interpreting the claim.

As the Examiner noted, "the specification provides no specific definition" of the phrase "viable primate embryo." The Examiner, however, then interpreted the claim by looking to possible uses of an embryo: "[the] only contemplated uses for the embryos that are produced by the claimed methods are either for the production [of] viable, cloned primates, or to use the viable embryos to produce embryonic stem ["ES"] cells." Office Action at 7. The Examiner then went on to exclude the possibility of using embryos to produce ES cells: "Examiner does not address the contemplated use of the embryo with regard to the production of ES cells, because Applicants did not elect this invention (see Election, 6/1/06, of Group I, directed to producing a cloned animal)." Office Action at 8. The Examiner concluded that the claims must be read to require production of a cloned animal – "[t]hus, the claims are [sic] extent they read on the elected invention." *Id.* In short, the Examiner not only inappropriately interpreted "viable primate embryo" by reference to its possible uses, the Examiner considered only the use of the embryo to produce a cloned animal. This twisted reasoning led the Examiner to read the language "producing a cloned animal" – the very language Applicants deleted from the claims – back into the claims for purposes of the Examiner's enablement analysis and thus creating the straw man necessary for the Examiner to improperly perpetuate the present rejection.

The Examiner's reasoning is flawed in several respects. Viable has an accepted meaning in the art. For example, more than one dictionary defines the term as "capable of living." *See, e.g.*, The American Heritage Dictionary of the English Language, Fourth Edition (2006) (http://dictionary.reference.com/browse/viable) ; Merriam-Webster's Medical Dictionary (2002) (http://dictionary.reference.com/browse/viable) (copies of these definitions are submitted concurrently in an Information Disclosure Statement). The Examiner ignores this accepted ordinary meaning of "viable." In addition, the Examiner ignores

the express definition of "embryo" in the specification: "the term 'embryo' . . . as used herein includes a developing cell mass that has not implanted into the uterine membrane of a maternal host." Specification at [0032]. Simply stated, a "viable primate embryo" is one that is a developing cell mass that is capable of living. There is nothing in this meaning that requires production of a cloned animal. Indeed, the Examiner must give credence to the Applicants own definition, which is explicitly inapposite to the Examiner's position. Indeed, the Examiner's interpretation of the claims is improper and it is this broader view that the Examiner improperly relied upon to conclude that the claims are not enabled.

B. The Examiner Relies Upon Art Showing Unpredictability in Using NT to Produce Cloned Animals, Not in Producing Viable Embryos.

Once the proper scope of the claimed invention is acknowledged, the case for enablement becomes far clearer. As Applicants argued in their response to the Office Action mailed on August 15, 2006, the references cited by the Examiner show unpredictability in producing cloned animals. Indeed, the Examiner recognizes this fact: "[T]he prior art of record (e.g., Oback, Campbell et al., Tian et al., and Li et al.) are pertinent to the claimed invention with regard to the unpredictability in using any donor cell in methods of nuclear transfer, to produce a cloned primate. These references provide the state of the art of nuclear transfer, in a general sense, with regard to the unpredictability in producing viable, cloned animals." Office Action at 8. The Examiner goes on to acknowledge that these references "do not provide specific guidance with regard to the production of primate embryos." *Id.* Moreover, in the Office Action mailed on August 15, 2006, the Examiner acknowledges that the Oback reference shows that of the 5% of the 200 different mammalian cell types that have been tested as nuclear donors "they all support development to blastocysts." August 15, 2006 Office Action at 7 (citing Oback at p. 147, Col. 2). These references are thus entirely irrelevant to the analysis of the properly interpreted currently-pending claims.

The Examiner does argue that Ng and Chen are references that are somehow relevant to show that there is great unpredictability in using NT to produce viable primate embryos. However, the Examiner focuses on the suggestions in these references that removal of mitotic spindle may not be the only cause for the

developmental arrest of primate NT embryos. Office Action at 9. These references simply do not show that there is great unpredictability in producing viable primate embryos. In addition, as Applicants argued in their response to the August 15, 2006, Office Action, Chen and Ng do not support the proposition for which the Examiner cites them, especially in light of other art (for example, Zhou et al., *A comparative approach to somatic cell nuclear transfer in the rhesus monkey*, Human Reproduction, 21(10), 2564, 2569 (2006) (which is submitted concurrently, as requested by the Examiner, in an Information Disclosure Statement), states "The NuMA turbulence associated with disordered chromosome organization that was found in some SCNT-produced embryos in this study was consistent with development failure.").

In short, the Examiner does not present evidence of unpredictability of production of viable primate embryos. Therefore, Applicants request the Examiner reconsider and withdraw the rejection of the pending claims for lack of enablement.

C. Applicants' Proposed Amendment to Claim 1 Eliminates Any Perceived Insufficiencies of Disclosure Regarding Combinations of Molecular Components

The Examiner stated that the specification is deficient because it "provides no specific guidance as to what combination(s) of the recited molecular components would be sufficient to produce a viable primate embryo." Office Action at 9. Applicants respectfully traverse.

Without acquiescing to propriety of the Examiner's rejection, and specifically the Examiner's interpretation of what the present application teaches or supports, and solely in an effort to expedite prosecution and place the present application in condition for allowance, Applicants propose an amendment to Claim 1 that deletes the Markush group that recited multiple molecular components. As amended, the claims would recite only the use of "a centrosomal component from a sperm centrosome." If the Examiner enters such an amendment, the claim itself would direct the skilled artisan to one particular molecular component and the Examiner's rejection would be moot.

D. The Examiner Ignores the Teachings that are in the Specification.

The Examiner repeatedly refers to the "lack of teachings or guidance" provided by the specification. Office Action at 12. However, the Examiner seemingly ignores the disclosure that is in the specification, the most important part of which is a working example and Applicants respectfully traverse.

Importantly, the working example describes use of the invention with cells of a rhesus monkey. Rhesus monkeys "are the major primates used in biomedical research." U.S. Patent No. 5,843,780 (which is submitted concurrently in an Information Disclosure Statement), Col. 6, ll. 25-27; *see also id.* at Col 6, ll. 30-34 ("Because of the extremely close anatomical and physiological similarities between humans and rhesus monkeys, rhesus monkey true ES cell lines provide a very accurate in vitro model for human differentiation."); Zhou et al., p. 2564 ("Owing to similarities with humans, the rhesus monkey is considered a clinically relevant animal model for biomedical research and for determining the safety and efficacy of new therapies."). The working example shows the use of enucleated rhesus monkey oocytes as recipient cells, and various donor cells, including "dissociated granulosa cells, endothelial cells collected from rhesus umbilical cords, isolated, cultured ICM cells derived from rhesus blastocytes (2-3 passages), and primary rhesus fibroblast cell lines." Specification at [0059].. The working example also shows that "rhesus sperm extract" was injected after cell fusion. *Id.*.

That a single or few examples may be sufficient to enable broader claims is a fundamental principle in U.S. patent law. For example, in *Amgen v. Hoechst*, the Federal Circuit held a claim to any "vertebrate cell" capable of producing a particular recombinant protein was enabled by a disclosure containing only one or two examples. 314 F.3d 1313, 1335-36 (Fed. Cir. 2003). Here, the claims do not recite broad terms or factors and ingredients that lead to a myriad of possible embodiments. Here, the claims are not drawn to all animals (or even all vertebrates), but are instead limited to the relatively small group of primates. Thus, the group of donor and recipient cells for the claimed method are not overly broad. In addition, the proposed amendments to Claim 1 recite the use of only one molecular component, instead of a group of molecular components (as discussed in section II.C above).

Importantly, "the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation must not be unduly extensive."

Chiron v. Genentech, 363 F.3d 1247, 1253 (Fed. Cir. 2004) (quotations and citations omitted). The example provides specific guidance on which donor cells to use, which recipient cells to use, and which molecular components to add. *See, e.g.*, Specification at [0059]. In this case, given that "one of ordinary skill in the art would have a high level of skill" (Office Action at 6), it is would only be a matter of routine trial and error to bridge any gaps between the disclosure and the claim scope.

E. The Examiner Did Not Analyze the Additional Limitation Contained in Claim 85.

Applicants added Claim 85 in their response to the Office Action mailed on Aug. 15, 2006. Claim 85 depends from Claim 1 and adds the limitation: "wherein said nucleus is obtained from a donor cell selected from the group consisting of a dissociated granulose cell, an endothelial cell, an isolated ICM cell derived from a blastocyst and a primary fibroblast cell line." Claim 85 thus further defines the subject matter of Claim 1 to the use of particular donor cells. Despite this amendment, the Examiner does not separately address this claim in the enablement analysis. Validity is determined on a claim-by-claim basis, and the Examiner should consider the effect of the additional limitation in Claim 85, especially in light of the proposed amendments to Claim 1. Accordingly Applicants respectfully request that the Finality of the present Office Action be withdrawn and that prosecution be reopened for the proper consideration of the subject matter defined in Claim 85.

F. New Claim 86 is Clearly Enabled.

Applicants have added New proposed Claim 86 which recites: "The method according to claim 1 wherein said primate is a rhesus monkey." Given that the working example in the specification relates specifically to a rhesus monkey, there can be no doubt that New Claim 86 is enabled. As such, Applicants assert that New proposed Claim 86 is in condition for allowance.

III. CLAIM REJECTIONS UNDER 35 U.S.C. § 112, ¶2.

The Examiner rejected claims 1-16, 21 and 85 under 35 U.S.C. § 112, ¶2, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which Applicants regard as the invention. The Examiner found fault in Claim 1's failure to recite "a primate cell nucleus, and a primate enucleated oocyte." Office Action at 13. Applicants respectfully traverse.

Without acquiescing to propriety of the Examiner's rejection, and specifically the Examiner's interpretation of what the present application teaches or supports, and solely in an effort to expedite prosecution and place the present application in condition for allowance, Applicants have proposed amendments to Claim 1 to recite a "primate cell nucleus" and a "primate egg." Should the Examiner enter the proposed amendments, the Examiner's rejection would be rendered moot.

CONCLUSION

Applicants have properly stated and traversed each of the Examiner's grounds for rejection. Applicants note that the Examiner has withdrawn all rejections over the prior art and that the claims are therefore free of the prior art. Now that Applicants have addressed the Examiner's § 112 rejections, Applicants believe that the presented claims are in condition for allowance.

If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited. If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account.

Respectfully submitted,

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